

Prior Responses to Similar Comments (excerpted from Responsiveness Summary to Comments on BPSOU ROD)

Precautionary Principle

- “Our understanding of the Precautionary Principle is that proponents claim we don’t know enough about the health effects of a chemical and, hence, should remediate ALL of it, just to be safe. EPA strongly disagrees, especially for lead, arsenic, and mercury. We have an abundance of data from both human and animal studies that look at the systemic, reproductive, developmental, neurological, and cancer-causing potential of these inorganics. We know the adverse effects that are associated with these inorganics and the dose levels and exposure pathways at which these effects occur. We also have an abundance of information on how people are or could be exposed via soil, water, air, produce, etc. contaminated with these inorganics. As a result, we can quantitate how much lead, arsenic, or mercury; a person could be exposed to through various media and we can quantitate the probability of an adverse effect occurring. We can also reverse those calculations and quantitate concentration levels in media which are safe. We agree that there is some variability and/or uncertainty associated with those estimates. People differ in their physiology and behavior, sampling and analytical results vary, multiple chemicals can interact in competitive or synergistic ways, etc. However, that variability and uncertainty is recognized both qualitatively and quantitatively in the risk assessment process. Conservatism is incorporated into the risk assessment process to ensure that cleanup levels are protective of the reasonably maximum exposed individual and the most susceptible member of the population to the effects of that contaminant. Conservatism is also applied in the risk decision making process via the risk decision criteria. For example, the background rate for coming down with cancer in the U.S. is now 1 in 3 or 0.3. EPA recommends that no site should have contamination which exceeds a 0.0001 (and many times even lower) chance of cancer for the most highly exposed, most sensitive person. So the position that we don’t have enough information to make an informed risk or remediation decision and therefore need to remove everything is contrary to standard EPA Superfund practices.”

Action Levels

- “EPA believes the action levels are protective. We have an abundance of data from both human and animal studies that look at the systemic, reproductive, developmental, neurological, and cancer-causing potential of these inorganics. We know the adverse effects that are associated with these inorganics and the dose levels and exposure pathways at which these effects occur. We also have an abundance of information on how people are or could be exposed via soil, water, air, produce, etc. contaminated with these inorganics. As a result, we can quantitate how much lead, arsenic, or mercury; a person could be exposed to through various media and we can quantitate the probability of an adverse effect occurring. We can also reverse those calculations and quantitate concentration levels in media which are safe. We agree that there is some variability and/or uncertainty associated with those estimates. People differ in their physiology and behavior, sampling and analytical results vary, multiple chemicals can interact in

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- "The action levels developed for the BPSOU were based on site specific information. This explains why cleanup levels for Butte are different than other sites. In particular, clear scientific evidence was developed which showed Butte contaminants to be less bioavailable than wastes at other sites. In site specific calculations, the cumulative risks are calculated for an individual on the basis of chronic exposures, using reasonable maximum exposure (RME) assumptions by combining a statistically sound, arithmetic average, exposure point concentration with reasonable conservative values for intake and duration. Estimates for risk for current and reasonably anticipated future land uses and potential future ground water and surface water used, without institutional controls, are done as well. The risk analysis will clearly identify the population, or sub-group (e.g., highly exposed or susceptible individuals), for which risks are being evaluated."
- "In short, EPA's action levels are conservative, safe, and consistent with the law and EPA guidance. Site-specific data account for differences with other sites' action levels."
- "Conservatism is incorporated into the risk assessment process to ensure that cleanup levels are protective of the reasonably maximum exposed individual and the most susceptible member of the population as to the effects of that contaminant. Conservatism is also applied in the risk decision making process via the risk decision criteria. The NCP requires that remediated sites should not have contamination levels which exceed a 0.0001 or 10^{-4} (and many times even lower) chance of cancer for the most highly exposed, most sensitive person. The action levels for BPSOU represent a 0.00001, or 10^{-5} , chance of cancer, and also provide for safe levels of non-cancerous risk. The action levels are protective."
- "EPA has carefully considered and evaluated the human health risks in Butte, including cumulative risks. Through the previous response action work, nearly all source areas exceeding action levels have been addressed. The lead abatement program has addressed approximately 600 homes, many of which were a high priority. Under the remedy, many more Butte homes will be sampled and cleaned up. The Selected Remedy incorporates the systematic sampling of all homes in the BPSOU and includes a targeted component that prioritizes sampling and remediation for affected or sensitive citizens. Wastes left in place can be safely managed to prevent risk, and will be systematically evaluated for protectiveness through the Butte

Reclamation Evaluation System. The BSB metals abatement program will ensure permanent evaluation and O&M activities for residential properties.”

Health Risk Assessments

- “EPA uses conservative approaches in all of its risk assessments, and the risk assessments were done in accordance with the NCP and EPA guidance by experienced EPA risk assessors. ATSDR participated with EPA on many aspects of the risk assessments. In addition, several site-specific exposure studies have been conducted in Butte to ensure that risks have been properly assessed. EPA is confident that its risk assessments and resulting action levels and triggers are fully protective of human health.”
- “The BPSOU Baseline Human Health Risk Assessment for Arsenic determined that the sub-population of concern would include individuals with a protein deficient diet, as they may not be able to methylate arsenic to the less toxic form. The toxicity factors developed for arsenic are intended to be protective of any sensitive subpopulations. In addition, the toxicity factor for cancer is based on the conservative assumption that any level of arsenic can result in a cancer risk. Therefore it is assumed that any sensitive subpopulations of concern should be protected by the toxicity factors used in this specific risk analysis.”
- “The risk assessment quantitatively evaluated resident contact with attic dust and evaluated the likelihood that the attic dust was contributing arsenic, lead, or mercury to the living space house dust. The evaluation found that exposures to attic dust were below EPA levels of concern for both cancer and non-cancer effects for all likely users, based on a detailed use survey done in conjunction with ATSDR. The evaluation also found that the attic dust was not a significant contribution source to the inorganic levels measured in the living space house dust. The evaluation found that in the unusual situation where attics became actual living spaces or were significantly altered through remodeling which caused significant releases to living spaces, unacceptable risk was present. In these instances, the ROD requires prompt cleanup of attic dust to eliminate this risk.”
- “At the beginning of the risk assessment process for Walkerville, a blood lead and urinary arsenic testing program was set up by the County Health Department and EPA for residents of Walkerville. There were no elevated levels of arsenic found in the individuals who participated in the study. We haven’t received any reports of elevated levels of inorganic arsenic in the urine samples from medical doctors in the Butte area. However, that does not mean there have been no reported cases. Still, the Agency has not received notification of arsenic contamination in individuals. This supports EPA’s overall human health risk assessment for the BPSOU site.”
- “The IEUBK Model for lead was used to assess children’s exposure to lead and to calculate remediation goals for lead in soil. The IEUBK Model integrates exposures to lead from water, air, diet, soil, dust, maternal contribution, etc. to estimate exposure (and risk) and to calculate the PRGs. The PRGs for lead in soil do take into account the lead in water, air, diet, and (indirectly via house dust) paint and are protective given the current levels of lead in those non-soil sources at Butte. Site-specific lead bioavailability data were carefully reviewed and accepted for use by EPA experts. This is consistent with EPA guidance regarding risk assessment.”

Attics

- “The dust in attics in Walkerville and a few throughout the BPSOU have been sampled for lead, mercury and arsenic. Smelter emissions are a likely partial source for these contaminants, but other sources are possible. A number of homes had elevated levels of all three contaminants of concern. The analytical results from the attic dust sampling for lead, arsenic and mercury; can be found in the Baseline Human Health Risk Assessment document for Walkerville. We expect other houses in the BPSOU, which are near former smelters or mine waste dumps, to have similar levels. We did not do a comprehensive, BPSOU wide sampling effort because this wasn't necessary to complete the RI/FS or to select a remedy.”
- “The attic dust was analyzed for total arsenic, which includes all inorganic and organic forms, including trivalent arsenic. According to Dr. John Drexler, Professor of Geochemistry at UC Boulder, in an oxidizing environment, like the BPSOU pathways of concern, approximately 99 percent of the arsenic present would be in the pentavalent valence state. The presence of trivalent arsenic would be minimal, if at all. Examples of an oxidizing environment would be surface soil, surface waters, house dust, etc. Basically, any media where oxygen is present is an oxidizing environment.”